HOUSE BILL No. 1909

DIGEST OF INTRODUCED BILL

Citations Affected: IC 16-18-2; IC 16-42-21-2; IC 16-42-25; IC 25-26-13-4.

Synopsis: Drug company reports of gifts. Requires pharmaceutical manufacturers to report information concerning gifts and payments that are made to a person who prescribes or purchases prescription drugs. Excludes certain gifts and payments from disclosure. Provides that failure to disclose required information is a Class A infraction. Repeals a definition superseded by this act.

Effective: July 1, 2003.

Welch

January 23, 2003, read first time and referred to Committee on Public Health.

Introduced

First Regular Session 113th General Assembly (2003)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2002 Regular or Special Session of the General Assembly.

HOUSE BILL No. 1909

A BILL FOR AN ACT to amend the Indiana Code concerning health.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 16-18-2-37.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2003]: **Sec. 37.5. "Board", for purposes of IC 16-42-25, has the meaning set forth in IC 16-42-25-2.**

SECTION 2. IC 16-18-2-103 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2003]: Sec. 103. "Drug sample", for purposes of IC 16-42-21 ~~has the meaning set forth in IC 16-42-21-2.~~ **and IC 16-42-25, means a legend drug or controlled substance that is manufactured, packaged, labeled, or otherwise marketed to be distributed and dispensed without consideration.**

SECTION 3. IC 16-18-2-216 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2003]: Sec. 216. (a) "Manufacturer", for purposes of IC 16-42-19, ~~and~~ IC 16-42-21, **and IC 16-42-25,** means a person who by compounding, cultivating, harvesting, mixing, or other process produces or prepares legend drugs. The term includes a person who:

(1) prepares legend drugs in dosage forms by mixing,

compounding, encapsulating, entableting, or other process; or

(2) packages or repackages legend drugs.

(b) The term does not include pharmacists or practitioners (as defined in section 288(a) and 288(c) of this chapter) in the practice of their profession.

SECTION 4. IC 16-18-2-280.5. IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2003]: **Sec. 280.5. "Pharmaceutical marketer", for purposes of IC 16-42-25, has the meaning set forth in IC 16-42-25-3.**

SECTION 5. IC 16-42-25 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2003]:

Chapter 25. Drugs: Pharmaceutical Manufacturer Marketing Report

Sec. 1. This chapter does not apply to a wholesale drug distributor or distributor's representative who promotes or markets the services of the wholesale drug distributor in connection with a legend drug.

Sec. 2. As used in this chapter, "board" refers to the Indiana board of pharmacy established by IC 25-26-13-3.

Sec. 3. As used in this chapter, "pharmaceutical marketer" means a person who, while employed by or under contract to represent a manufacturer, engages in pharmaceutical detailing, promotional activities, or other marketing of a legend drug in Indiana to any physician, hospital, health care facility, pharmacist, health benefit plan administrator, or any other person authorized to prescribe, dispense, or purchase a legend drug.

Sec. 4. This chapter does not require a manufacturer to disclose the following:

(1) Drug samples intended to be distributed to patients.

(2) The payment of reasonable compensation and reimbursement of expenses in connection with an approved clinical trial conducted in connection with a research study designed to answer specific questions about vaccines, new therapies, or new ways of using known treatments.

(3) Any gift, fee, payment, subsidy, or other economic benefit, the value of which is less than twenty-five dollars ($25).

(4) Scholarships or other support for medical students, residents, and fellows to attend a significant educational, scientific, or policymaking conference of a national, regional, or specialty medical or other professional association if the

recipient of the scholarship or other support is selected by the association.

Sec. 5. (a) Before October 15 of each year, each manufacturer shall disclose, for the preceding twelve (12) month period ending June 30, to the board the value, nature, and purpose of any gift, fee, payment, subsidy, or other economic benefit provided in connection with detailing, promotional or other marketing activities by the manufacturer or through the manufacturer's pharmaceutical marketers to any physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person authorized to prescribe, dispense, or purchase legend drugs in Indiana.

(b) Each manufacturer subject to this chapter shall annually disclose to the board the name and address of the individual responsible for the manufacturer's compliance with the provisions of this chapter.

Sec. 6. (a) The board shall provide to the office of the attorney general complete access to the information disclosed under section 5 of this chapter.

(b) Before February 1 of each year, the office of the attorney general shall report to the general assembly and the governor on the manufacturers' disclosures made the preceding year under this chapter.

Sec. 7. (a) The board and the office of the attorney general shall keep confidential all trade secrets (as defined by IC 24-2-3-2) identified under this chapter.

(b) The disclosure form prescribed by the board must allow the manufacturer to identify any information that is a trade secret.

Sec. 8. (a) A person who violates this chapter commits a Class A infraction.

(b) The attorney general may bring an action for injunctive relief, costs, and attorney's fees against a manufacturer that fails to disclose information as required under section 5 of this chapter.

(c) Each failure to disclose information required under section 5 of this chapter constitutes a separate violation.

SECTION 6. IC 25-26-13-4 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2003]: Sec. 4. (a) The board may:

(1) promulgate rules ~~and regulations~~ under IC 4-22-2 for implementing and enforcing this chapter;

(2) establish requirements and tests to determine the moral, physical, intellectual, educational, scientific, technical, and professional qualifications for applicants for pharmacists'

licenses;

(3) refuse to issue, deny, suspend, or revoke a license or permit or place on probation or fine any licensee or permittee under this chapter;

(4) regulate the sale of drugs and devices in ~~the state of~~ Indiana;

(5) impound, embargo, confiscate, or otherwise prevent from disposition any drugs, medicines, chemicals, poisons, or devices which by inspection are deemed unfit for use or would be dangerous to the health and welfare of the citizens of the state of Indiana; the board shall follow those embargo procedures found in IC 16-42-1-18 through IC 16-42-1-31, and persons may not refuse to permit or otherwise prevent members of the board or their representatives from entering such places and making such inspections;

(6) prescribe minimum standards with respect to physical characteristics of pharmacies, as may be necessary to the maintenance of professional surroundings and to the protection of the safety and welfare of the public;

(7) subject to IC 25-1-7, investigate complaints, subpoena witnesses, schedule and conduct hearings on behalf of the public interest on any matter under the jurisdiction of the board;

(8) prescribe the time, place, method, manner, scope, and subjects of licensing examinations which shall be given at least twice annually; ~~and~~

(9) **administer the collection of information from pharmaceutical manufacturing companies under IC 16-42-25; and**

(10) perform such other duties and functions and exercise such other powers as may be necessary to implement and enforce this chapter.

(b) The board shall adopt rules under IC 4-22-2 for the following:

(1) Establishing standards for the competent practice of pharmacy.

(2) Establishing the standards for a pharmacist to counsel individuals regarding the proper use of drugs.

(c) The board may grant or deny a temporary variance to a rule it has adopted if:

(1) the board has adopted rules which set forth the procedures and standards governing the grant or denial of a temporary variance; and

(2) the board sets forth in writing the reasons for a grant or denial of a temporary variance.

SECTION 7. IC 16-42-21-2 IS REPEALED [EFFECTIVE JULY 1, 2003].

SECTION 8. [EFFECTIVE JULY 1, 2003] **(a) The definitions in IC 16-42-25, as added by this act, apply to this SECTION.**

(b) Notwithstanding IC 16-42-25-5(a), as added by this act, the initial disclosure shall be made before October 15, 2004, for the preceding twelve (12) month period ending June 30, 2004.

(c) Notwithstanding IC 16-42-25-5(b), as added by this act, each manufacturer subject to the provisions of this chapter shall disclose to the board, before October 15, 2003, the name and address of the individual responsible for the manufacturer's compliance with IC 16-42-25, as added by this act.

(d) This SECTION expires July 1, 2006.